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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,008	03/24/2004	Roger Cady	57294.019	5678

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HUSCH & EPPENBERGER, LLC
190 CARONDELET PLAZA
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ST. LOUIS, MO 63105-3441

EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1656

DATE MAILED: 12/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/808,008	Applicant(s) CADY, ROGER	
	Examiner Chih-Min Kam	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16, 22 and 24 is/are pending in the application.
- 4a) Of the above claim(s) 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 16, 22 and 24 are pending.

Applicants' amendment filed on October 14, 2005 is acknowledged. Applicants' response has been fully considered. Claims 14, 15, 17-21, 23 and 24 have been cancelled, and claim 22 has been amended, and a new claim 25 has been added. The newly added claim, claim 25, is directed to a non-elected invention, a topical solution for the treatment of a sensory neuron related disorder, thus it is withdrawn from consideration. Therefore, claims 16 and 22 are examined.

Withdrawn Claim Rejections - 35 USC § 112

2. The previous rejection of claims 14, 15 and 19 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's cancellation of the claims in the amendment filed October 14, 2005.

Withdrawn Claim Rejections - 35 USC § 102

3. The previous rejection of claims 14, 15, 18-21, 23 and 24 and 9 under 35 U.S.C. 102(e), as being anticipated by Donovan (US 2004/0009180), is withdrawn in view of applicant's cancellation of the claims in the amendment filed October 14, 2005.

Withdrawn Claim Rejections - 35 USC § 103

4. The previous rejection of claim 17 under 35 U.S.C. 103(a), as being unpatentable over Donovan (US 2004/0009180) in view of Ho *et al.* (U.S. Patent 5, 770, 567), is withdrawn in view of applicant's cancellation of the claims in the amendment filed October 14, 2005.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained, and claim 19 has been added.

Claim 22 recites the limitation "the neuropeptide" in line 11. There is insufficient antecedent basis for this limitation in the claim.

New Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 16 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donovan (US 2004/0009180).

Donovan teaches a pharmaceutical composition containing a botulinum toxin (e.g., botulinum toxin type A) and at least one enhancing agent for facilitating transdermal delivery of the botulinum toxin into a human patient (paragraph [0056]), wherein the pharmaceutical composition can be used to treat several types of disorders associated with neurotransmitter release (e.g., migraine, fibromyalgia or neurogenic inflammation; paragraphs [0043] and [0066]), and wherein the botulinum toxin can be lyophilized, reconstituted with saline or water, and an

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enhancing agent can be added to the composition (paragraphs [0069]-[0073]), where the enhancing agent refers to an agent that enhances the permeability of the patient's skin so that botulinum toxin can be absorbed by the skin to achieve a therapeutic effect, e.g., lecithin vesicles, and the enhancing agent excludes the combination of pluronic lecithin organogel (PLO) and DMSO (paragraph [0050]). The reference also indicates botulinum toxin may act on the sensory neurons to decrease the release of substance P or CGRP (calcitonin gene-related peptide) to reduce inflammation and pain associated with inflammation (paragraph [0085]). Although the reference does not specifically recite the use of PLO as enhancing agent, it indicates the use of lecithin vesicles as enhancing agent and it does not exclude the use of PLO alone (paragraph [0050]). At the time of invention was made, it would have been obvious that one of ordinary skill in the art is motivated to use a pharmaceutical composition containing botulinum toxin type A, saline and PLO as an enhancing agent for the treatment of migraine (claim 16) and inhibiting the release of neurotransmitter in trigeminal neurons to treat symptoms of migraine (claim 22) because PLO is a known topical and transdermal carrier (see Art of Record below), which can enhance the permeability of the patient's skin so that botulinum toxin can be absorbed by the skin to achieve a therapeutic effect. Therefore, the teachings of Donovan result in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

Conclusion

7. No claims are allowed.

Art of Record

Archer *et al.* (U.S. Patent 5,976,547, published November 2, 1999) teach topical analgesic and antiphlogistic blended compositions which are useful for reducing inflammation,

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where transdermal opioid analgesics are blended in either pluronic lecithin organogel (PLO) or a petrolatum base; Kryger (U.S. Patent 6,743,448, filed December 11, 2001) teaches a topical testosterone formulation comprising micronized testosterone, an arginine and a tocopherol ingredient admixed with a PLO.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner



CHIH-MIN KAM
PATENT EXAMINER

CMK

December 2, 2005